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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/519,076	03/06/00	SALKOFF	L 8512-00130US

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EXAMINER

BASIN
ART UNIT PAPER NUMBER

1646 5
DATE MAILED: 06/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/519,076

Applicant(s)
Salkoff et al

Examiner
Nirmal. S. Basi

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 6, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1646

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825
5 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825 within the statutory period set for response to this office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be
10 obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

2. Claims 1 to 44 are pending in the instant application.

15 Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 17-18 and 20 in so far as they encompass a purified polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in class 530, subclass 350.

II. Claims 17, 19 and 21, in so far as they encompass a purified polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in class 530, subclass 350.

Art Unit: 1646

III. Claims 17, 19 and 21, in so far as they encompass a purified polypeptide comprising the amino acid sequence of SEQ ID NO:16, classified in class 530, subclass 350.

IV. Claims 17, 19 and 21, in so far as they encompass a purified polypeptide comprising the amino acid sequence of SEQ ID NO:18, classified in class 530, subclass 350.

5 V. Claims 1-2, 4, 6, 8, 10, 12-15 and 26-27, in so far as they encompass an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in class 536, subclass 23.5.

10 VI. Claims 1, 3, 7, 9, 11-14, and 26-27, in so far as they encompass an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in class 536, subclass 23.5.

VII. Claims 1, 3, 5, 7, 9, 11-14, 16 and 26-27, in so far as they encompass an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:16, classified in class 536, subclass 23.5.

15 VIII. Claims 1, 3, 5, 7, 9, 11-14, 16 and 26-27, in so far as they encompass an isolated polynucleotide encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:18, classified in class 536, subclass 23.5.

IX. Claims 22 and 23 in so far as they encompass a purified antibody which binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:1, classified in class 530, subclass 388.22.

Art Unit: 1646

X. Claims 24 in so far as it encompasses a purified antibody which binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:3, classified in class 530, subclass 388.22.

5 XI. Claims 24 and 25 in so far as they encompass a purified antibody which binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:16, classified in class 530, subclass 388.22.

XII. Claims 24 and 25 in so far as they encompass a purified antibody which binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:18, classified in class 530, subclass 388.22.

10 XIII. Claim 28-30, 31 and 33, in so far as they encompass method for identifying a compound that increases or decreases ion flux through pH sensitive potassium channel comprising the amino acid sequence of SEQ ID NO:1, classified in class 435, subclass 7.1 for example.

XIV. Claim 28-30, and 32, in so far as they encompass method for identifying a compound that increases or decreases ion flux through pH sensitive potassium channel comprising
15 the amino acid sequence of SEQ ID NO:3, classified in class 435, subclass 7.1 for example.

XV. Claim 28-30, 32 and 34, in so far as they encompass method for identifying a compound that increases or decreases ion flux through pH sensitive potassium channel comprising the amino acid sequence of SEQ ID NO:16, classified in class 435, subclass 7.1 for example.

Art Unit: 1646

XVI. Claim 28-30, 32 and 34, in so far as they encompass method for identifying a compound that increases or decreases ion flux through pH sensitive potassium channel comprising the amino acid sequence of SEQ ID NO:18, classified in class 435, subclass 7.1 for example.

XVII. Claim 35-37, drawn to method for detecting the presence of Slo3 in mammalian tissue, classified in class 435, subclass 7.1 for example.

XVIII. Claims 38-39 drawn to computer system and method for screening for mutations of Slo3 genes, classified in class 702, subclass 20.

XIX. Claims 40-44 drawn to computer system, method for identifying a three dimensional structure of Slo proteins, classified in class 702, subclass 22.

The inventions are distinct, each from the other because:

The proteins that are inventions I to IV, the nucleic acids that are inventions V to XIII, the antibodies that are inventions IX-XII are independent, structurally and functionally different distinct chemical compounds, each of which can be made and used without any one or more of the other compounds.

The proteins that are inventions I to IV are related to the nucleic acids of Invention V to XIII by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification

Art Unit: 1646

from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization.

The proteins of Invention I to IV are related to antibodies of Invention IX-XI by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementary of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right or in assays for the identification of agonists of the protein.

The proteins that are inventions I to IV are each related to the methods that are inventions XIII-XVII as products and processes of using those products. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The proteins that are inventions I to IV can be used in a method of producing antibody, which is a method that is materially different from the methods of inventions XIII-XVII.

The products of Invention IV to XII are distinct from the method of Invention XIII to XIX wherein the products of Invention IV to XII can neither be used in nor made by the method of Invention XIII to XIX.

Art Unit: 1646

The product of Invention I to IV are distinct from the method of Invention XVIII-XIX wherein the products of Invention I to IV can neither be used in nor made by the method of Invention XVIII-XIX.

5 The methods of Inventions IV to XIX are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

10 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-XIX would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

15 Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Art Unit: 1646

Advisory Information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
June 22, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Application No.: 09/519 076

**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE